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No. 07-1068

IN THE
Supreme Court of the United States

NUCLEONICS, INC.,
Petitioner,

v.

BENITEC AUSTRALIA, LTD.,
Respondent.

On Petition For A Writ Of Certiorari To The United States Court of Appeals For The Federal Circuit

BRIEF IN OPPOSITION

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QUESTIONS PRESENTED

1. Whether the Federal Circuit correctly found, based on the particular facts of this case, that speculative future infringement that may never materialize does not support declaratory judgment jurisdiction?

2. Whether the Federal Circuit correctly found, based on the particular facts of this case, that jurisdiction over declaratory judgment claims ended with patentee's covenant not to sue for infringement, when the covenant was made before the District Court had tried the case or issued any decision on the merits?

RULE 29.6 STATEMENT

Benitec Australia, Ltd. is 100% owned by Benitec UK, Ltd., which is 100% owned by Benitec Limited, a public company listed on the Australian Securities Exchange.

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CONSTITUTIONAL AND STATUTORY PROVISIONS INVOLVED

> It shall not be an act of infringement to make, use, offer to sell, or sell within the United States or import into the United States a patented invention (other than a new animal drug or veterinary biological product (as those terms are used in the Federal Food, Drug, and Cosmetic Act and the Act of March 4, 1913) which is primarily manufactured using recombinant DNA, recombinant RNA, hybridoma technology, or other processes involving site specific genetic manipulation techniques) solely for uses reasonably related to the development and submission of information under a Federal law which regulates the manufacture, use, or sale of drugs or veterinary biological products.

35 U.S.C. § 271(e)(1).

STATEMENT OF THE CASE

A. Introduction

This case presents a unique procedural and factual posture that does not warrant granting certiorari. The Federal Circuit has correctly applied the precedents of this Court relating to declaratory judgment jurisdiction to the facts of this case. Simply put, there is no case or controversy currently existing between the parties.

While the petition suggests that Benitec Australia, Ltd. ("Benitec") brought suit for testing in mice and rabbits (Pet. 5-6), it fails to admit that

these activities were asserted by Nucleonics, Inc. ("Nucleonics") to be animal testing for human therapeutic use, as opposed to animal therapeutic use or testing for animal therapeutic use. As explained below, Benitec owns the rights to animal testing for human use but a non-party to this lawsuit owns the rights to animal testing for animal use.

B. The Parties, Patent, and Technology

The petition incorrectly characterizes the respondent as a patent "troll." Pet. 8. In fact, Benitec is a biotechnology company engaged in developing technologies to treat serious diseases and advancing medical research using gene silencing technologies. *Benitec Austl. Ltd. v. Nucleonics, Inc.*, 495 F.3d 1340, 1342 (Fed. Cir. 2007) ("*Benitec*"), Pet. App. 2a. *See also* J.A. 70-71 ¶¶ 2, 9.[1] Benitec's work involves human therapeutic use of double-stranded RNA ("dsRNA" or "ddRNA"), often referred to as interference RNA ("iRNA"). Human therapeutic use of iRNA is covered by the claims of the patent-in-suit, U.S. Patent No. 6,573,099 ("the '099 Patent"). The '099 Patent also covers use of iRNA in animals other than humans. J.A. 68-69.

The ownership as well as the rights to practice the '099 Patent are currently divided between Benitec and Australian non-party Commonwealth Scientific and Industrial Research Organization ("CSIRO"), with each holding a discrete bundle of rights. J.A. 1528-52.

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[1] References to "J.A." are to the Confidential Joint Appendix submitted to the Federal Circuit on June 13, 2006.

Specifically, Benitec has the exclusive right to commercialize the '099 Patent in the "Human Field," which includes the use of the technology in humans and any use of the technology in animal research for testing the technology for human use. J.A. 1530 at (B)(a); J.A. 1536 ¶ 2.2; J.A. 1532(a-c). In contrast, CSIRO has the exclusive right to commercialize the '099 Patent in non-human fields, including the "Animal Field," which includes use of the technology in animals and testing in animals for animal use. J.A. 1530 at (B)(b); J.A. 1536 ¶ 3; J.A. 1530-31(a-h).

Benitec also has the right to sublicense its human therapeutic use and animal testing for human use, but the right to sublicense the use of the technology in the Animal Field belongs exclusively to CSIRO. J.A. 1536-37 ¶ 4.3. Thus, Benitec has exclusive patent rights relating to humans, while CSIRO has exclusive rights in the animal field.

Nucleonics, Inc. ("Nucleonics")

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On April 1, 2004, long after the issuance of the '099 Patent, Nucleonics announced that it had raised $49.2 million in venture capital financing to pursue therapeutic use of iRNA. J.A. 2748-49. *See also* J.A. 1410 ¶ 11.

C. Proceedings Below

1. District Court Proceedings

On March 22, 2004, Benitec sued Nucleonics for infringement of the '099 Patent. Benitec had filed suit against Nucleonics as its competitor for human therapeutic use of iRNA and had argued that animal testing for human use was infringing activity.

Nucleonics' April 30, 2004 answer to the complaint did not include any counterclaims. J.A. 75-78.

On July 13, 2004, Nucleonics moved to dismiss the action for lack of jurisdiction based on 35 U.S.C. § 271(e)(1), asserting that all of its activities, including animal-related activities, would fall within the safe harbor. *Benitec*, 495 F.3d at 1342, Pet. App. 2a-3a. Nucleonics unambiguously represented to the District Court and Benitec that "Benitec has shot before there is even a target" because "Nucleonics' accused activities are directed to developing and submitting information to the [FDA] and are therefore exempt from infringement under [§ 271(e)(1)]." *Id.* at 1342, Pet App. 2a-3a. *See also* J.A. 2656. Nucleonics further asserted that "Benitec lacks a statutory basis to sue for infringement at this time, and it is premature for this Court even to entertain such a claim.

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[2] The FDA must approve an IND before clinical trials (*i.e.*, human testing) can be conducted.

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In support of its motion, Nucleonics submitted declarations by Dr. Satishchandran, Nucleonics' co-founder and Vice President for Research and Development. J.A. 2666-76, J.A. 2798-801. Dr. Satishchandran averred that:

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Thus, Nucleonics repeatedly represented to the District Court and Benitec that all of its work fell within the scope of the § 271(e) safe harbor. Throughout discovery, Nucleonics maintained this position and never sought to supplement its discovery responses with the position it now embraces in an attempt to defeat dismissal in the District Court. Neither the Federal Circuit dissent nor Nucleonics' petition to this Court mention Nucleonics' motion or declaration.

Benitec's opposition to Nucleonics' motion to dismiss relied primarily upon the Federal Circuit's decision in *Integra Lifesciences I, Ltd. v. Merck KGaA*, 331 F.3d 860 (Fed. Cir. 2003) ("*Integra*"), *vacated*, 545 U.S. 193 (2005). J.A. 2696-702. The Federal Circuit had held that pre-clinical

experiments to screen and identify potential new drug candidates did not qualify for safe harbor protection under § 271(e)(1). In deciding that pre-clinical research is not exempt from infringement, the Federal Circuit held that "[t]he safe harbor does not reach any exploratory research that may rationally form a predicate for future FDA clinical tests." *Integra*, 331 F.3d at 867. Thus, the Federal Circuit held that the safe harbor exemption did not reach back down the research chain to protect the earliest stages of screening and research for potential drug candidates. *Id.* at 867.

Based on the Federal Circuit's subsequently-overruled *Integra* decision, Benitec had argued that Nucleonics' research activities extended beyond the scope of the § 271(e)(1), and thus were not protected by the safe harbor exemption. The District Court agreed and denied Nucleonics' motion to dismiss on February 7, 2005. J.A. 2850. The District Court noted, however, that "the Supreme Court may possibly reverse the Federal Circuit's holding in *Integra*". *Id.* Accordingly, the court denied Nucleonics' motion "with leave to renew in the event the *Integra* case is reversed." *Id.* *See also Benitec*, 495 F.3d at 1342, Pet. App. 3a.

On February 16, 2005, Nucleonics sought leave to file an amended answer, which for the first time included a counterclaim seeking declaratory judgment that the '099 Patent was invalid and unenforceable. J.A. 252-65. The District Court granted Nucleonics leave on September 14, 2005. J.A. 23.

On June 13, 2005, this Court decided *Merck KGaA v. Integra Lifesciences I, Ltd.*, which vacated

the Federal Circuit's *Integra* ruling and clarified the broad range of activities that § 271(e)(1) exempts from infringement. 545 U.S. 193, 207 (2005) ("*Merck*"). In view of *Merck* and the District Court's prior ruling, on August 1, 2005, Benitec moved to dismiss the case without prejudice pursuant to Fed. R. Civ. P. 41(a)(2). J.A. 1373-74. Benitec explained that, in light of this Court's decision and Nucleonics' previous representations to the District Court,

> Benitec could only bring new claims if Nucleonics is ultimately successful in obtaining FDA approval for its infringing products or otherwise engages in infringing activities not otherwise permitted under the § 271(e) exemption. Nucleonics' original motion, which the [District] Court indicated it would reconsider if the law were changed by [this Court's decision in the] *Integra* case, is essentially a motion for dismissal for lack of jurisdiction because there can be no case or controversy if the § 271(e)(1) exemption applies. There is no basis for this Court to dismiss with prejudice infringement claims that do not yet exist. Accordingly, Benitec respectfully requests that the Court dismiss this case without prejudice.

J.A. 1379. Benitec's reply reiterated that it "has no basis to continue to assert its claims." J.A. 1508 (emphasis added).

Despite the unambiguous nature of the statements Nucleonics made to the District Court in its own motion to dismiss on the same § 271(e)(1) grounds, Nucleonics opposed Benitec's motion for

dismissal and made self-contradictory statements. In support of its opposition, Nucleonics filed a declaration of its President and CEO, Robert Towarnicki ("Towarnicki"). J.A.1408-13. Towarnicki asserted that Nucleonics "wishes" to expand its business to include animal husbandry and veterinary products, and that Nucleonics has had "discussions" with an unknown breeding stock supplier. *Benitec*, 495 F.3d at 1348, Pet. App. 18a. *See also* J.A. 1412 ¶ 20. There is, however, no other evidence in the record regarding Nucleonics' "wishes" or the nature and scope of any such discussions.

Towarnicki also asserted that Nucleonics had "signed an agreement" with a "pharmaceutical" company to work on an "exploratory collaboration". Nucleonics' "Petition For Rehearing And Rehearing En Banc", filed August 3, 2007, *available at* 2007 WL 2434249, ("Pet. for Reh'g") at 4. *See also* J.A. 1410-11. As with Nucleonics' vague "discussions", there is no other evidence in the record regarding the nature, scope, or progress of any such "exploratory collaboration", nor is there any explanation of how such work with a "pharmaceutical" company could possibly fall outside of the protection of the 35 U.S.C. § 271(e)(1) safe harbor.

The District Court granted Benitec's motion on September 29, 2005. *Benitec Austl. Ltd. v. Nucleonics, Inc.*, 2005 U.S. Dist. Lexis 22008 (D. Del. Sept. 29, 2005), Pet. App. 36a-45a. Nucleonics appealed.

Benitec represented to the Federal Circuit that "[t]o the extent that there is any ambiguity in the record, Benitec's motion [to dismiss] included — and

was intended to include — a promise not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the District Court's September 29, 2005 dismissal order...." Non-Confidential Brief Of Plaintiff-Appellee Benitec Australia, Ltd., filed April 27, 2006, *available at* 2006 WL 1433923, at 12 (citation omitted). *See also Benitec*, 495 F.3d at 1343, Pet. App. 5a. Thus, Benitec has unconditionally covenanted not to sue Nucleonics for patent infringement arising from activities and/or products occurring on or before the date dismissal was entered in this action — September 29, 2005.[3] *See Sierra Applied Sciences, Inc. v. Advanced Energy Indus., Inc.*, 363 F.3d 1361, 1375-76 (Fed. Cir. 2004) (statements by attorney in colloquy with the District Court, in Federal Circuit brief, and at oral argument constituted a promise to forebear from suing).

After this Court issued *MedImmune, Inc. v. Genentech, Inc.*, 127 S.Ct. 764 (2007), both parties

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[3] To the extent that Nucleonics complains that Benitec's covenant does not include a covenant not to sue for the

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Nucleonics has never withdrawn these sworn declarations and it is most reasonable to presume they are still correct. Moreover, Benitec could not include the rights for animal use in animal therapeutics in its covenant not to sue because it neither owns nor controls these rights, which are owned by CSIRO. J.A. 1528-52; A1530 at (B)(b); J.A. 1530-31(a-h); J.A. 1536-37 ¶ 4.3. *See, e.g., Pope Mfg. Co. v. Gormully & Jeffery Mfg. Co.*, 144 U.S. 248, 250 (1892).

filed supplemental briefs on that decision with the Federal Circuit.

2. Federal Circuit Affirmance

The Federal Circuit affirmed the District Court's dismissal in an opinion that followed this Court's precedent, despite Nucleonics' attempts to mischaracterize it.

The Federal Circuit recognized that if "'a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction' at that time." *Benitec*, 495 F.3d at 1344; Pet. App. 9a, (quoting *Cardinal Chem. Co. v. Morton Int'l*, 508 U.S. 83, 96 (1993)). Nucleonics' assertion that "the majority gave no further credence to *Cardinal Chemical*" regarding jurisdiction (Pet. 13) is incorrect. The Federal Circuit recognized that "once that burden [of establishing jurisdiction] has been met, *absent further information*, that jurisdiction continues." *Benitec*, 495 F.3d at 1344-45; Pet. App. 9a-10a (citing *Cardinal*, 508 U.S. at 98).

The Federal Circuit further noted that "'[i]f a party to an appeal suggests that the controversy has, since the rendering of the judgment below, become moot, that party bears the *burden of coming forward* with subsequent events that have produced that alleged result.'" *Benitec*, 495 F.3d at 1345, Pet. App. 10a (quoting *Cardinal*, 508 U.S. at 98; emphasis added by Federal Circuit). The Federal Circuit then addressed the fact-intensive events subsequent to the filing of this litigation that have divested jurisdiction. *Benitec*, 495 F.3d at 1345-49, Pet. App. 11a-22a.

Nucleonics also incorrectly alleges that the Federal Circuit's analysis of whether any of Nucleonics' asserted activities supported jurisdiction was "except in name, a clear return to the disapproved 'reasonable apprehension of imminent lawsuit' test." Pet. 28. Nucleonics ignores the fact that in *MedImmune*, this Court held that for declaratory judgment jurisdiction to exist, the dispute must be "definite and concrete"; "real and substantial"; and of "*sufficient immediacy and reality* to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771 (emphasis added). In accordance with *MedImmune*, the Federal Circuit assessed whether Nucleonics' asserted activities had "sufficient immediacy and reality" to present a case or controversy. *See, e.g., Benitec*, 495 F.3d at 1346, 1348-49, Pet. App. 14a, 19a-20a, 22a-23a.

Nucleonics' petition for rehearing and petition for rehearing *en banc* was denied.

3. USPTO Reexamination

On October 4, 2004, Nucleonics initiated a third party reexamination of the '099 Patent at the U.S. Patent and Trademark Office ("USPTO"). *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1. On May 18, 2006, Nucleonics requested a second reexamination of the '099 Patent. *Id.* On October 26, 2006, the USPTO merged these two reexaminations, and they are still pending. *Id.*; U.S. Reexamination Nos. 90/007,247 and 90/008,096 (*see http://portal.uspto.gov/external/portal/pair*).

In its first reexamination request, Nucleonics claimed that the '099 Patent was invalid for alleged indefiniteness and lack of written description and

provided the USPTO with art that Nucleonics asserted invalidated the '099 Patent. J.A. 1616-17. Nucleonics' second request added more art that it asserted invalidated the patent. U.S. Reexamination No. 90/008,096.

Although the USPTO issued rejections of the claims over art provided by Nucleonics, the USPTO did not base any rejections on Nucleonics' claims of indefiniteness or lack of written description. U.S. Reexamination Nos. 90/007,247 and 90/008,096. Benitec has responded to all rejections and has cancelled claims. *Id.* The merged reexamination proceeding is still pending. *Id.*

REASONS FOR DENYING THE PETITION

This case presents no issue meriting the Court's attention. First, the Federal Circuit's decision in this case is intricately bound to an unusual, complicated, and disputed set of facts. Thus, the decision lacks the broad import attributed to it by Nucleonics. Second, the decision does not conflict with any decisions of this Court. Third, the Federal Circuit's decision correctly applied the law to the unusual posture of this case.

A. The Decision Is Intricately Bound To An Unusual, Complicated, And Disputed Set Of Facts And Lacks Broad Applicability.

Nucleonics' assertions of the importance of the opinion in this case "to defendants in every patent infringement suit" is absurd in view of the fact-dependant nature of the opinion. The Federal Circuit's opinion did not set forth any broad or original pronouncements of law, even in dicta.

Rather, the opinion consists of (a) a detailed exploration of the facts, including the existence of relevant factual issues that are not resolved because the facts were not provided to the District Court or are not yet in existence and (b) application of existing law of this Court and the Federal Circuit to the specific facts. The Federal Circuit based its jurisdictional decision on the following specific factors:

- Benitec moved to dismiss its claims before any trial or decision on infringement (*Benitec*, 495 F.3d at 1343, 1347-48, Pet. App. 4a-5a, 16a-17a);
- Benitec covenanted not to sue Nucleonics based on activities that had already occurred (*Benitec*, 495 F.3d at 1343, 1347-48, Pet. App. 5a, 17a);
- Nucleonics was not presently engaging in any potentially infringing activity, and its plans for future potentially infringing activity were not definite or concrete (*Benitec*, 495 F.3d at 1346-47, 1348-50, Pet. App. 13a-15a, 17a-21a);
- after Benitec filed suit, this Court clarified the § 271(e)(1) safe harbor such that it became evident that Nucleonics' only current or imminent activities of any commercial interest to Benitec are shielded from claims of infringement (*Benitec*, 495 F.3d at 1342, 1349, Pet. App. 4a, 20a-22a);
- before Benitec moved to dismiss the case for lack of jurisdiction, Nucleonics had moved to dismiss on the same grounds (*Benitec*, 495 F.3d at 1342, Pet. App. 2a-3a); and

- the patent-at-issue is currently being reexamined (*see, e.g.*, *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1) and may emerge with different claims.

The impact of the Federal Circuit opinion has likewise been limited. In cases citing *Benitec* in which the intellectual property owner sued for infringement or could otherwise have been characterized as asserting its intellectual property at the time of filing of the suit in question, then successfully sought to have counterclaims challenging its intellectual property dismissed for lack of jurisdiction, either the intellectual property owner provided a covenant not to sue that satisfied the court that there was no longer any case or controversy, the intellectual property owner had filed a formal statutory disclaimer with the USPTO (thereby, prohibiting any suit for infringement of the disclaimed patent), or the court found that the party seeking a declaratory judgment had not shown current, or concretely-planned future, possibly infringing activity. *See Monsanto Co. v. Syngenta Crop Prot., Inc.*, 2008 U.S. Dist. Lexis 7236 (E.D. Mo. Jan. 31, 2008) (finding both that patent owner's conduct did not show willingness and preparedness to enforce its patent and that declaratory plaintiff did not show current or planned infringing activity); *Vantage Trailers, Inc. v. Beall Corp.*, 2008 U.S. Dist. Lexis 7133 (S.D. Tex. Jan. 31, 2008); *Furminator, Inc. v. Kim Laube & Co.*, 2008 U.S. Dist. Lexis 1105 (E.D. Mo. Jan. 7, 2008); *Pfizer Inc. v. Ranbaxy Labs.*, 525 F. Supp. 2d 680 (D. Del. 2007); *Merck & Co. v. Apotex, Inc.*, 2007 U.S. Dist. Lexis 84426 (D.N.J. Nov. 15, 2007); *MMJK, Inc. v. Ultimate Blackjack*

Tour LLC, 2007 U.S. Dist. Lexis 85502 (N.D. Cal. Nov. 7, 2007); *Furminator, Inc. v. Ontel Prods. Corp.*, 246 F.R.D. 579 (E.D. Mo. 2007); *Abbott Labs. v. Baxter Healthcare Corp.*, 2007 U.S. Dist. Lexis 76449 (N.D. Ill. Sept. 28, 2007); *Crossbow Tech., Inc. v. YH Tech.*, 2007 U.S. Dist. Lexis 65646 (N.D. Cal. Aug. 21, 2007).

In cases citing *Benitec* in which the intellectual property owner sued for infringement or could otherwise have been characterized as asserting its intellectual property at the time of filing of the suit in question, and did not provide a satisfactory covenant or disclaimer, the District Courts retained jurisdiction. *Boston Sci. Corp. v. Johnson & Johnson Inc.*, 2008 U.S. Dist. Lexis 5510 (D. Del. Jan. 24, 2008); *Cordance Corp. v. Amazon.com, Inc.*, 521 F. Supp. 2d 340 (D. Del. 2007); *Sabert Corp. v. Waddington N. Am., Inc.*, 2007 U.S. Dist. Lexis 68092 (D.N.J. Sept. 14, 2007); *FieldTurf USA, Inc. v. Sports Constr. Group, LLC*, 507 F. Supp. 2d 801 (N.D. Ohio 2007). *See also Teva Pharm. Indus. v. Reddy's Labs.*, 2008 U.S. Dist. Lexis 16958 (D.N.J. Mar. 4, 2008) (denying summary judgment motion for lack of case or controversy as to claim for which patentee provided covenant not to sue, but denying summary judgment motion on the merits without prejudice to refile as to claim for which no covenant was provided); *MedImmune, Inc. v. Genentech, Inc.*, 2008 U.S. Dist. Lexis 12198 (C.D. Cal. Feb. 7, 2008) (granting motion to dismiss claims for declaratory judgment of invalidity and unenforceability of patent claims as to which patentee provided covenant not to sue, but retaining jurisdiction over claims for

declaratory judgment on patent claim as to which no covenant was provided).

The Federal Circuit's other decisions applying *MedImmune* illustrate that it is correctly applying this Court's precedent and also that jurisdiction is found to exist in the majority of cases. In the nine cases other than *Benitec* in which the Federal Circuit applied *MedImmune* to determine whether jurisdiction existed, it found that jurisdiction was lacking in only one. *Maxwell v. Stanley Works, Inc.*, 2008 U.S. App. Lexis 323 (Fed. Cir. Jan. 8, 2008). In seven cases, the Federal Circuit found that jurisdiction did exist, although it found that discretionary dismissal had been proper in one of these (*Cellco*) and might be proper on remand in another (*Sony*). *Micron Tech., Inc. v. Mosaid Techs.*, Inc., 2008 U.S. App. Lexis 4387 (Fed. Cir. Feb. 29, 2008); *Adenta GmbH v. OrthoArm, Inc.*, 501 F.3d 1364 (Fed. Cir. 2007); *Honeywell Int'l Inc. v. Universal Avionics Sys. Corp.*, 488 F.3d 982 (Fed. Cir. 2007); *Teva Pharm. USA, Inc. v. Novartis Pharm. Corp.*, 482 F.3d 1330 (Fed. Cir. 2007); *SanDisk Corp. v. STMicroelectronics, Inc.*, 480 F.3d 1372 (Fed. Cir. 2007); *Cellco P'ship v. Broadcom Corp.*, 227 Fed. Appx. 889 (Fed. Cir. 2007); *Sony Elecs., Inc. v. Guardian Media Techs., Ltd.*, 497 F.3d 1271 (Fed. Cir. 2007). In one case, the court did not determine whether jurisdiction existed, but vacated and remanded for consideration in light of *MedImmune*. *Baker Hughes Oilfield Operations, Inc. v. Reedhycalog UK, Ltd.*, 228 Fed. Appx. 988 (Fed. Cir. 2007).

Indeed, a finding of jurisdiction in this case would improperly open all patent holders, whether

licensing the patent or not, to expansive threats of declaratory judgment action for mere patent ownership. Nucleonics essentially argues that present activities that do not infringe and undefined, hypothetical future activities can support jurisdiction under the Declaratory Judgment Act. Adopting Nucleonics' standard would confer jurisdiction to nearly anyone abstaining from any contemplated action, no matter how theoretical or remote in time, because they feared they might someday be sued for infringement. Thus, it is the result desired by Nucleonics that would result in grave and widespread harm — to every patent owner.

B. Nucleonics' Petition Seeks To Broaden Declaratory Judgment Jurisdiction To Obtain An Unconstitutional Advisory Opinion.

Article III jurisdiction is limited to the resolution of cases and controversies. *Valley Forge Christian College v. Americans United for Separation of Church and State, Inc.*, 454 U.S. 464, 471 (1982); *Sierra Applied Sciences*, 363 F.3d at 1372; *Travelers Ins. Co. v. Obusek*, 72 F.3d 1148, 1153-54 (3d Cir. 1995). The requirement for the existence of a case or controversy is not relaxed in cases under the Declaratory Judgment Act. *See Obusek*, 72 F.3d at 1153.

A controversy "must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts." *Aetna Life Ins.*

Co. v. Haworth, 300 U.S. 227, 241 (1937). "Basically, the question in each case is whether the facts alleged, under all the circumstances, show that there is a substantial controversy, between parties having adverse legal interests, of sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *Maryland Cas. Co. v. Pacific Coal & Oil Co.*, 312 U.S. 270, 273 (1941). Here, the degree of immediacy and reality required to create jurisdiction is not present. This fact-specific finding does not convert this case into one of Constitutional importance.

An action or counterclaim brought under the Declaratory Judgment Act, 28 U.S.C. § 2201, *et seq.*, may not be used to obtain an advisory opinion on a hypothetical state of facts. *Calderon v. Ashmus*, 523 U.S. 740, 746 (1998); *Obusek*, 72 F.3d at 1153-54 ("The existence of a 'case or controversy' is a condition precedent to the proper exercise of judicial power by a federal court and the Declaratory Judgment Act can not relax that constitutional requirement."); *Arrowhead Indus. Water v. Ecolochem*, 846 F.2d 731, 736 (Fed. Cir. 1988) (A declaratory plaintiff is not entitled to "an advisory opinion on whether it would be liable for patent infringement if it were to initiate some merely contemplated activity."), *overruled in part by MedImmune*, 127 S. Ct. at 774 n.11 (rejecting Federal Circuit's use of "reasonable-apprehension-of-suit test"). Nucleonics' attempt to obtain an advisory opinion when there is insufficient immediacy and reality to support a declaratory judgment action should be rejected, and the petition for certiorari should be denied.

Additionally, a party wishing to challenge the validity of a patent is not without recourse if it cannot establish declaratory judgment jurisdiction: it may file a reexamination of the patent in the USPTO and even participate in it. In fact, that is precisely what Nucleonics has done here. On October 4, 2004, Nucleonics initiated a third party Reexamination challenging the validity of the '099 Patent. On May 18, 2006, Nucleonics requested yet another reexamination of the '099 Patent. *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1. On October 26, 2006, the USPTO merged these two reexaminations, and they are still pending. *Id.*; U.S. Reexamination Nos. 90/007,247 and 90/008,096 (*see http://portal.uspto.gov/external/portal/pair*). Thus, the claims with which the '099 Patent will emerge from reexamination are not known.

C. The Federal Circuit's Decision Does Not Conflict With *Cardinal* or *Altvater*.

The Federal Circuit's analysis recognized that if "'a party has actually been charged with infringement of the patent, there is, *necessarily*, a case or controversy adequate to support jurisdiction' at that time." *Benitec*, 495 F.3d at 1344, Pet. App. 9a (quoting *Cardinal*, 508 U.S. at 96). It further recognized that "once that burden [of establishing jurisdiction] has been met, *absent further information*, that jurisdiction continues." *Benitec*, 495 F.3d at 1344-45, Pet. App. 9a-10a (citing *Cardinal*, 508 U.S. at 98). The Federal Circuit also noted that "'[i]f a party to an appeal suggests that the controversy has, since the rendering of the judgment below, become moot, that party bears the

burden of coming forward with subsequent events that have produced that alleged result.'" *Benitec*, 495 F.3dat 1345, Pet. App. 10a (quoting *Cardinal*, 508 U.S. at 98; emphasis added by Federal Circuit).

Cardinal recognized that a change in circumstances can divest jurisdiction: "[i]f, before the court had decided the case, either party had advised it of a material change in circumstances that entirely terminated the party's controversy, it would have been proper either to dismiss the appeal or to vacate the entire judgment of the District Court." 508 U.S. at 98. *See also id.* at 97 (If "[the Federal Circuit] had jurisdiction while the case was pending before it, the case remains alive (*barring other changes*) when it comes to us.") (emphasis added); *United States v. Munsingwear*, 340 U.S. 36, 39 (1950) (a case that becomes moot should be reversed or vacated and remanded for dismissal); *Steffel v. Thompson*, 415 U.S. 452, 459 n.10 (1974) (an "actual controversy must be extant at all stages of review, not merely at the time the complaint is filed.").

In the instant case, there were material changes in circumstances that entirely terminated the controversy. Specifically, (1) this Court's holding in *Merck*, in combination with (2)

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and that it did not plan to seek FDA approval to manufacture and market a prospective drug product until at least 2012, if ever (3) as a result, Nucleonics' activities could not be found to be infringing, and (4) Benitec covenanted not to sue Nucleonics for any activities before the date that District Court dismissed the suit.

Further, the Federal Circuit's determination that *Cardinal* "did not hold that the ultimate burden of proof in the trial court was on other than the party seeking to invoke declaratory judgment jurisdiction" (*Benitec*, 495 F.3d at 1345, Pet. App. 10a-11a) is fully in accord with this Court's decision in *Cardinal*. By its own terms, *Cardinal* is limited to circumstances where a party is seeking to vacate a judgment. *See, e.g., Cardinal*, 508 U.S. at 100 ("the burden of demonstrating that changed circumstances provide a basis for *vacating the judgment* of patent invalidity rests on the party that seeks such action") (emphasis added); *id.* at 95 (The "issue before [this Court in *Cardinal* concerned] the jurisdiction of an intermediate appellate court — *not the jurisdiction of either a trial court or this Court. In the trial court, of course, a party seeking a declaratory judgment has the burden of establishing the existence of an actual case or controversy.*") (emphasis added).

As the Federal Circuit had previously recognized:

> The question actually before the Supreme Court in *Cardinal* was "whether the affirmance by the Court of Appeals for the Federal Circuit of a finding that a patent has not been infringed is a sufficient reason," by itself, "for vacating a declaratory judgment holding the patent invalid." [*Cardinal*, 508 U.S. at 85]. The Court answered in the negative, but noted "that factors in an unusual case might justify [the Federal Circuit's] refusal to reach the merits of a validity determination," *id.* at [102], making the decision a relatively narrow one. In other

> words, according to *Cardinal*, a claim for a declaratory judgment of invalidity is independent of the patentee's charge of infringement in the following — and only the following — way: an affirmed finding of noninfringement does not, without more, justify a reviewing court's refusal to reach the trial court's conclusion on invalidity.

Super Sack Mfg. Corp. v. Chase Packaging Corp., 57 F.3d 1054, 1060 (Fed. Cir. 1995), *overruled in part by MedImmune*, 127 S. Ct. at 774 n.11 (rejecting Federal Circuit's use of "reasonable-apprehension-of-suit test").[4]

Thus, *Cardinal* did not hold or even suggest that "the ultimate burden of proof in the trial court was on other than the party seeking to invoke declaratory judgment jurisdiction." *Benitec*, 495 F.3d at 1345, Pet. App. 10a-11a. *Cardinal* did not even make any such statement in dicta.

The Federal Circuit properly found that *Cardinal* does not apply to District Court jurisdiction, particularly where that Court has not rendered any judgment on the merits. *Cardinal* states that the consideration perhaps "most important is the interest of the successful litigant in preserving the value of a declaratory judgment that... 'it obtained on a valid counterclaim at great effort and expense.'" 508 U.S. at 99 (quoting *Morton Int'l v. Cardinal Chem.*, 967 F.2d 1571, 1577 (Fed. Cir. 1992) (Nies, C.

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[4] Although *MedImmune* rejected the "reasonable-apprehension-of-suit test" (127 S. Ct. at 774 n.11), the rejected test was not used to support *Super Sack*'s finding regarding the applicability of *Cardinal*.

J., dissenting from denial of rehearing en banc). *Cardinal* also decried "the wasteful consequences of relitigating the validity of a patent after it has once been held invalid in a fair trial" occasioned by routinely vacating judgments of invalidity. *Id.* at 100-01. *See also Super Sack*, 57 F.3d at 1060 (where, as in the instant case, "the trial court neither made a finding on infringement nor reached a conclusion on validity[,] *Cardinal*, addressed to the propriety of appellate jurisdiction over final judgments respecting infringement and validity, simply does not apply.") This particular rationale for the *Cardinal* decision has no relevance to cases, such as the instant case, in which there is no successful litigant, there is no judgment on the merits, and there has been no trial.

Nor is the Federal Circuit's decision in conflict with *Altvater v. Freeman*. 319 U.S. 359 (1943). In *Altvater*, the District Court decided the case on the merits, finding non-infringement and invalidity, but the Eighth Circuit vacated the invalidity decision on the basis that the non-infringement ruling had mooted the counterclaims. *Id.* at 362-63. This Court reversed and remanded. *Id.* at 365-66. Unlike in the instant case, the *Altvater* declaratory plaintiff's claims were not moot because there was no intervening event between filing and judgment on the merits — such as a covenant not to sue — that divested the court of jurisdiction. Here, there were intervening events.

D. The Federal Circuit's Decision Does Not Conflict With *MedImmune*

Nucleonics alleges that the Federal Circuit's analysis of whether any of Nucleonics' asserted activities supported jurisdiction was "except in name, a clear return to the disapproved 'reasonable apprehension of imminent lawsuit' test." Pet. 28. Nucleonics ignores the fact that in *MedImmune*, this Court held that for declaratory judgment jurisdiction to exist, the dispute must be "definite and concrete"; "real and substantial"; and of "*sufficient immediacy and reality* to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771 (emphasis added). In accordance with *MedImmune*, the Federal Circuit properly assessed whether Nucleonics' asserted activities had "sufficient immediacy and reality" to present a case or controversy. *See, e.g., Benitec*, 495 F.3d at 1346, 1348-49, Pet. App. 14a, 19a-20a, 22a-23a.

Nucleonics, in alleging that its asserted vague "wishes" and potential future activities support jurisdiction to challenge the validity of claims of a patent that may emerge from reexamination with substantially different claims, would remove the long-standing requirements for immediacy and reality from the case or controversy requirement. *See, e.g., Haworth*, 300 U.S. at 241 (a controversy "must be a real and substantial controversy admitting of specific relief through a decree of a conclusive character, as distinguished from an opinion advising what the law would be upon a hypothetical state of facts."); *Arrowhead Indus.*, 846 F.2d at 736 (declaratory plaintiff not entitled to "an

advisory opinion on whether it would be liable for patent infringement if it were to initiate some merely contemplated activity."). Even the Federal Circuit dissent agreed that: "[i]f this declaratory judgment action were filed today... the required case or controversy had not been established" and "the future controversy would not satisfy the sufficient immediacy and reality test for the filing of a new suit today...." *Benitec*, 495 F.3d at 1350, 1354, Pet. App. 23a, 33a.

Significantly, in *MedImmune* itself, the threat of harm avoided by petitioner's continuing royalty payments would otherwise have been "*imminent*". 127 S. Ct. at 772 (emphasis added). Thus, the teaching of *MedImmune* is that declaratory judgment jurisdiction exists when "Petitioner's own acts... eliminate the *imminent* threat of harm." *Id.* (emphasis added). In the instant case, Nucleonics is simply not faced with "'imminent' injury in fact fairly... trace[able] to" any concrete action by Benitec. *Id.* at 772 n.8 (citation omitted).

For Nucleonics' activities prior to the District Court's dismissal of the suit, Benitec's covenant not to sue destroyed any "substantial controversy" between the parties. Based on the facts of this case, including the scant and hypothetical information provided to the Court by Nucleonics, Nucleonics' later activities are not "definite and concrete" or "real and substantial" enough and are not of "sufficient immediacy and reality to warrant the issuance of a declaratory judgment." *MedImmune*, 127 S. Ct. at 771; *Benitec*, 495 F.3d at 1346, 1348-49, Pet. App. 14a, 19a-20a, 22a-23a.

1. Nucleonics' Activities Related To Human Use Do Not Support Jurisdiction.

In its motion to dismiss, Nucleonics itself represented that

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J.A. 2662. *See also* J.A. 2659, J.A. 2661-63.

After *Merck* was decided by this Court, Benitec recognized that Nucleonics was exempt from infringement under 35 U.S.C. § 271(e)(1). *See, e.g.*, J.A. 1379. As the Federal Circuit stated, Benitec and Nucleonics "have now both taken the position that Nucleonics' present activities related to the human medical application of RNAi are, in light of § 271 and the Supreme Court's decision in *Merck*, not infringing and cannot become infringing until after Nucleonics files a new drug application ('NDA')...." *Benitec*, 495 F.3d at 1347, Pet. App. 14a. *See also id.*, 495 F.3d at 1342, Pet. App. 3a (Nucleonics

asserted that an NDA will not be filed until at least 2010-12); J.A. 2663. Thus, Nucleonics' activities reasonably related to human use of RNAi, including animal testing, are exempt from current infringement liability and will be exempt for many years.

The record does not support any showing that a controversy of sufficient immediacy and reality exists between Benitec and Nucleonics. Nucleonics may never file an NDA, and any product or technique approved by the FDA may not come within the scope of the claims of the '099 Patent. This is particularly true since a reexamination of the '099 Patent is pending. *See, e.g.*, *Benitec*, 495 F.3d at 1342, n.1, Pet. App. 3a-4a, n.1. It is therefore not known what, if any, claims may exist by the time Nucleonics may file an NDA. Indeed, even Nucleonics admits that it may be many years until it files an NDA. Accordingly, any controversy regarding Nucleonics' human applications of RNAi lacks the requisite reality and immediacy to support declaratory judgment jurisdiction.

2. Nucleonics' Purported Wish To Expand Its Efforts Does Not Support Jurisdiction.

After Benitec moved to dismiss, Nucleonics asserted for the first time that it "wishes to expand its efforts beyond human health to animal husbandry[,]"and had "executed a confidentiality agreement" as a "prerequisite to detailed technical discussions" for possible work. *Benitec*, 495 F.3d at 1348, Pet. App. 18a. *See also* J.A. 1412 ¶ 20. This vague wish does not create jurisdiction. The

described activity is largely speculative, describing generally what might someday happen. Further, as properly found by the Federal Circuit, the concrete acts that Nucleonics did describe do not constitute infringement under 35 U.S.C. § 271(a). *Benitec*, 495 F.3d at 1348-49, Pet. App. 17a-21a. *See, e.g., Rotec v. Mitsubishi*, 215 F.3d 1246, 1254-55 (Fed. Cir. 2000).

Even if Nucleonics does eventually engage in activity within the scope of current or reexamined claims, § 271(e)(1) would likely exempt them, in view of

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and (2) the wide breadth of activities that are protected: § 271(e)(1) "exempt[s] from infringement *all* uses of patented compounds 'reasonably related' to the process of developing information for submission under *any* federal law regulating the manufacture, use, or distribution of drugs." *Merck*, 545 U.S. at 206. *See also id.* at 208 ("We thus agree with the Government that the use of [patented technology] in preclinical studies is protected under §271(e)(1) *as long as there is a reasonable basis for believing that the experiments will produce 'the types of information that are relevant to an IND or NDA.'*" (emphasis added)). Thus, infringing activity may never occur.

Furthermore, given the broad scope of the § 271(e)(1) safe harbor, any non-safe harbor activities performed or products produced by Nucleonics would necessarily be in the area of animal therapy or research for animal therapy, with no application to human therapy. As Benitec explained before the Federal Circuit, it would have

no interest in suing Nucleonics in this area, in which it does not have commercialization rights and does not compete: the expense of a lawsuit to assert another party's rights does not make good business sense. Plaintiff-Appellee Benitec Australia, Ltd.'s Response to Defendant-Appellant Nucleonics' Supplemental Brief, filed March 5, 2007, at 6-8. *See also* J.A. 1528-52; J.A. 1530 at (B)(b); J.A. 1530-31(a-h); J.A. 1536-37 ¶ 4.3; *Benitec*, 495 F.3d at 1349, Pet. App. 21a ("Benitec has never challenged use of the technology in testing in animals for animal use and claims another company owns any right to do so.").

Additionally, Benitec would be precluded from suing Nucleonics over any activities or products in the animal arena without joining CSIRO, which owns the rights to the '099 Patent in the animal field. It has long been the law that, in order for patent infringement plaintiffs to have standing, the patent owner must be joined.[5] *See, e.g.*, *Independent Wireless Tel. Co. v. Radio Corp. of Am.*, 269 U.S. 459, 468 (1926). In the context of licensing, this Court has explained:

> [t]he patentee or his assigns may, by instrument in writing, assign, grant and convey, either, 1st, the whole patent, comprising the exclusive right to make,

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[5] Since the 1966 amendment of Federal Rule of Civil Procedure 19, "[a]s a general rule, [the Federal Circuit] continues to adhere to the principle set forth in *Independent Wireless* that a patentee should be joined, either voluntarily or involuntarily, in any infringement suit brought by an exclusive licensee." *Prima Tek II, L.L.C. v. A-Roo Co.*, 222 F.3d 1372, 1377 (Fed. Cir. 2000).

> use and vend the invention throughout the United States; or, *2d, an undivided part or share of that exclusive right*; or, 3d, the exclusive right under the patent within and throughout a specified part of the United States.... A transfer of either of these three kinds of interests is an assignment, properly speaking, and vests in the assignee a title in so much of the patent itself, *with a right to sue infringers; in the second case, jointly with the assignor*; in the first and third cases, in the name of the assignee alone."

Waterman v. Mackenzie, 138 U.S. 252, 255 (1891) (citation omitted; emphasis added).

The division of rights to the '099 Patent corresponds to the second situation in *Waterman*: each of Benitec and CSIRO have an undivided part of the patent — the right to practice in humans or animals, respectively — each having their part of the patent right throughout the United States. *See also Pope Mfg. Co.*, 144 U.S. at 250 (addressing the question "whether a patentee can split up his patent into as many different parts as there are claims, and vest the legal title to those claims in as many different persons" and recognizing the rule that the patent monopoly "is for one entire thing, and that in order to enable the assignee to sue, the assignment must convey to him the entire and unqualified monopoly which the patentee held, in the territory specified, and that any assignment short of that is a mere license.").

The Federal Circuit has explicitly set forth the application of this rule to the co-owner relationship,

stating "[e]ven an ownership interest, however, would not be sufficient to give [putative patent co-owner] IBEP prudential standing to sue for infringement, as *IBEP would have to join all the other co-owners in order to establish such standing.*" *Israel Bio-Engineering Project v. Amgen Inc.*, 401 F.3d 1299, 1304-05 (Fed. Cir. 2005) (emphasis added)). "Absent the voluntary joinder of all co-owners of a patent, a co-owner acting alone will lack standing." *Israel Bio-Engineering Project v. Amgen Inc.*, 475 F.3d 1256, 1264-65 (Fed. Cir.), *cert. denied*, 168 L. Ed. 2d 720 (2007).

Thus, CSIRO, an Australian research organization, would be a necessary party to resolution of any claim regarding animal rights. Because Benitec simply does not hold any of the bundle of rights to animal therapy or animal research for animal therapy, CSIRO is a necessary party even though a contract between CSIRO and Benitec, which was effective at the time that Benitec filed suit and at the time it filed its motion to dismiss, suggests that Benitec has the ability to file suit. *See, e.g., Propat Int'l Corp. v. RPost, Inc.*, 473 F.3d 1187, 1192 (Fed. Cir. 2007) (a right to sue clause did not confer the exclusive licensee with standing to sue since the plaintiff did not hold enough of the bundle of rights).

Nucleonics' vague wish to enter the animal field does not provide a basis for jurisdiction here.

3. Nucleonics' Alleged Agreement With A "Pharmaceutical" Company Does Not Support Jurisdiction.

After Benitec filed for dismissal, Nucleonics asserted that it had signed an agreement to work with a "pharmaceutical" company on an "exploratory collaboration" but that it did not perform due to vague "concerns about this litigation". Pet. for Reh'g at 4. *See also* J.A. 1410-11. Nucleonics asserts that its choice to stop this unspecified pre-dismissal work supports jurisdiction over its declaratory judgment claims because "*MedImmune* specifically holds that declaratory judgment jurisdiction is not defeated where a putative infringer — by virtue of coercion resulting from the patentee's threats — abstains from allegedly infringing activity that, if otherwise engaged in, would have supported jurisdiction" and complains that the Federal Circuit "departe[d] from *MedImmune*" in not considering "the fact that Nucleonics was coerced to end a collaboration, involving allegedly infringing activity...." Pet. 30-31. The Federal Circuit did not, however, need to decide whether *MedImmune* set such a low standard, as Nucleonics' asserted activity does not meet even this standard.

Nucleonics first raised this vague collaboration after Benitec moved to dismiss the litigation. Thus, Benitec never considered, much less alleged, that this collaboration was infringing. Indeed, despite pertinent discovery requests by Benitec, Nucleonics never provided Benitec enough information to even consider the question. Thus, referring to the collaboration as "allegedly infringing" is

disingenuous, especially in view of Nucleonics' statements that all of its research findings would become part of an IND submission to the FDA.

In its petition for rehearing by the Court of Appeals, Nucleonics asserted that this collaboration would "not [be] within the safe harbor [of § 271(e)(1)]". Pet. for Reh'g at 4. This unsworn attorney assertion is belied by (1)

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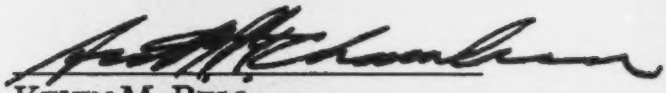
(*see* section III.A, *supra*); (2) the only information provided in Nucleonics' sworn declaration describing this work suggests that it *would* fall within the safe harbor (Pet. for Reh'g at 4 (describing the work as "exploratory collaboration" with a "pharmaceutical" company)); and (3) the breadth of the safe harbor, which makes it likely that any work in any way relevant to the use of the technology in humans would be exempt from infringement. Thus, on the factual record, the alleged corroboration does not support the exercise of jurisdiction.

CONCLUSION

For the foregoing reasons, the petition for a writ of certiorari should be denied.

Dated March 20, 2008

Respectfully submitted,



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